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| APPROVED BY: | SUPERSEDES | ORIGINAL ISSUE DATE | DISTRIBUTION LEVEL(S) |
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| // Director | | | |

PURPOSE

- 1.1 To protect the privacy of Patient Health Information (PHI) by removing information that is individually identifiable when it is not necessary for the intended purpose of the use or disclosure.
- 1.2 To establish requirement for de-identification and re-identification of PHI, as well as the creation and use of limited data sets.

POLICY

- 2.1 It is the policy of the Department of Mental Health (DMH) to set forth requirements for deidentification and re-identification of PHI. PHI is de-identified when the identifiers listed in Procedure Section 3.1.1 have been removed and there is no reasonable basis to believe the information can be used to identify a person. De-identified information is not PHI.
- 2.2 Unless otherwise restricted or prohibited by other federal or state law, DMH can use and share information as appropriate for the work of DMH, without further restriction, if DMH or another entity has taken steps to de-identify the information consistent with the requirements and restrictions of this policy.
- 2.3 DMH may use or disclose a limited data set that meets the requirements of this policy, if DMH enters into a data use agreement with the limited data set recipient (or with the data source, if DMH will be the recipient of the limited data set) in accordance with the requirements of this policy.

PROCEDURE

- 3.1 Requirements for De-identification of Protected Health Information
 - 3.1.1 PHI may be de-identified by removing eighteen (18) specific identifiers of the individual or of the relatives, employers or household members of the individual, provided the entity does not have knowledge that the information could be used alone or in combination with other information to identify the individual who is the subject of the information. The eighteen (18) specific identifiers are:



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- Names
- > All geographic subdivisions smaller than a state, including
 - Street address
 - City
 - County
 - Precinct
 - Zip code and equivalent geocode except if the initial 3 digits of a zip code:
 - Represents a geographic unit in which combining all zip codes with the same initials contains more than 20,000 people, and
 - The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to "000".
- All elements of dates (except year) directly related to an individual, including:
 - Birth date
 - Admission date
 - · Discharge date
 - · Date of death, and
 - All ages over 89 (including data elements indicative of such age [including year], except when all ages of 90 or older can be aggregated into a single category.
- > Telephone numbers
- Fax numbers
- E-mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers (including license plate numbers)
- Devise identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internal Protocol (IP) Address numbers



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- Biometric identifiers, including finger/voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code, except for a code of other means of re-identification as described in Section 3.2 below, and
- 3.1.2 DMH has no actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.

3.2 Re-identification Requirements

- 3.2.1 DMH may assign a code or other means of record identification to allow de-identified information to be re-identified provided the following conditions are met:
 - The code or other means of record identification is not derived from or related to information about the individual.
 - DMH does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism used for re-identification, and
 - DMH determines how and where these codes for re-identification are located and kept secure.
- 3.2.2 Disclosure of the code or other means of record identification is considered a disclosure of PHI.

3.3 Requirements for a Limited Data Set

- 3.3.1 A limited data set is information that excludes the following direct identifiers of the individual, or of relatives, employers or household members of the individual.
 - Names
 - Postal address information, other than town, state and zip code
 - > Telephone numbers
 - Fax numbers
 - E-mail addresses
 - Social Security numbers



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- Medical record numbers
- Health plan beneficiary numbers (such as Medi-Cal numbers)
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images.
- 3.3.2 A limited set may retain the following identifiers of the individual, or of the relatives, employers or household members of the individual:
 - Fown or city, state and zip code; and
 - Any element of dates directly related to an individual, including birth date, admission date, discharge date and date of death.
- 3.3.3 A limited data set may be used or disclosed only for the purposes of research, public health or health care operations.
- 3.3.4 DMH need not track or account for disclosures of limited data sets in an accounting of disclosures requested by an individual.

3.4 Contents of a Data Use Agreement

- 3.4.1 DMH may disclose a limited data set only if the entity receiving the limited data set enters into a written Data Use Agreement (Attachment I) with DMH, in accordance with subsection 3.4.2 immediately below, that such entity will use or disclose the Protected Health Information only as specified in the written agreement.
- 3.4.2 A data use agreement between DMH and the recipient of the limited data set must:
 - Specify who is permitted to use or receive the limited data set.
 - Specify that the limited data set recipient will:



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- Not use or further disclose the information other than as specified in the data use agreement or as otherwise required by law;
- Use appropriate safeguards to prevent use or disclosure of the information other than as specified in the data use agreement;
- Report to DMH, if DMH is the source of the limited data set, if the recipient becomes aware of any use or disclosure of the information not specified in its data use agreement with DMH;
- Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
- Not identify the information or contact the individuals whose data is being disclosed.
- 3.5 If DMH knows of a pattern of activity or practice of the limited data set recipient that constitutes a material breach or violation of the data use agreement, DMH will take reasonable steps to cure the breach or end the violation, as applicable, and, if such steps are unsuccessful, DMH will:
 - Discontinue disclosure of PHI to the recipient; and
 - Report the problem to the Secretary of the United States Department of Health and Human Services.
- 3.6 If DMH receives a limited data set from another covered entity, DMH must abide by the terms of a data use agreement.

DOCUMENT RETENTION

4.1 All documents required to be created or completed under this policy and procedure will be retained for a period of at least seven (7) years from the date of its creation or the date when it was last in effect, whichever is later.



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<u>AUTHORITY</u>

Code of Federal Regulations 45 Parts 160 and 164; Section 164.514(a)(c)(e). "Other Requirements Relating to Uses and Disclosures of Protected Health Information"

Code of Federal Regulations 45 Parts 160 and 164; Section 164.502(d). "Uses and Disclosures of Protected Health Information: General Rules – Uses and Disclosures of De-Identified Protected Health Information"

ATTACHMENT

Attachment I Data Use Agreement



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DMH'S DATA USE AGREEMENT

| This Data Use Agreement ("Agreement") is entered into effective this | day of 200_ ("Effective |
|--|-------------------------|
| Date"), by and between DMH ("Covered Entity") and | ("Data Set Recipient") |

RECITALS

WHEREAS, Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996, and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations Parts 160 and 164 ("Privacy Regulations");

WHEREAS, the Privacy Regulations require Covered Entity to enter into an agreement with Data Set Recipient in order to mandate certain protections for the privacy and security of Protected Health Information, and those Regulations prohibit the disclosure to or use of a Limited Data Set by Data Set Recipient if such an agreement is not in place;

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

DEFINITIONS

- 1.1 "<u>Disclose</u>" and "<u>Disclosure</u>" mean, with respect to the Limited Data Set, the release, transfer, provision of access to, or divulging in any other manner of the Limited Data Set outside Data Set Recipient's internal operations or to other than its employees.
- 1.2 "<u>Limited Data Set</u>" means Protected Health Information that excludes certain direct identifiers of the individual, or of relatives, employers, or household members of the individual as set forth at 45 C.F.R. § 164.512(e)(2).
- 1.3 "Required By Law" means a mandate contained in law that compels an entity to make a Use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or any administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing benefits.
- 1.4 "<u>Use</u>" or "<u>Uses</u>" mean, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Data Set Recipient's internal operations.



2.5

or contact the individuals.

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1.5 Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Regulations.

OBLIGATIONS OF DATA SET RECIPIENT

| 1 | <u>Permitted Uses and Disclosures of the Limited Data Set</u> . Data Set Recipient: |
|---|---|
| | |
| | |
| | (a) shall Use or Disclose the Limited Data Set only for the following purpose(s): |
| | i. The limited data set is to be used by only the Data Set Recipient. |
| | ii. The limited data set is to be used for: |
| | |
| | |
| | iii. The Limited Data Set shall not be Used or Disclosed for any other purpose by the D Set Recipient. |
| | (b) shall not Use or further Disclose the information other than as permitted by this Agreem or as otherwise Required By Law. |
| | <u>Adequate Safeguards</u> . Data Set Recipient shall Use appropriate safeguards to prevent the Use or Disclosure of the information other than as provided by this Agreement. |
| | Reporting Non-Permitted Use or Disclosure. Data Set Recipient shall report to Covered Er any Use or Disclosure of the information not permitted by this Agreement of which recipies becomes aware. |
| | <u>Use of Subcontractors and Agents</u> . Data Set Recipient shall require each of its agents and subcontractors that receive the Limited Data Set to execute a written agreement obligating agent or subcontractor to comply with the terms of this Agreement. |

Prohibition on Identification and Contact. Data Set Recipient shall not identify the information



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TERM AND TERMINATION

| 3.1 | This Agreement is effective (date) and ex | pires | _ (date). |
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| 3.2 this Ag | Upon Covered Entity's knowledge of a material b greement, Covered Entity shall either: | reach or violation b | by Data Set Recipient of |
| | (a) Provide an opportunity for Data Set Recipient atte this Agreement if Data Set Recipient does not opecified by Covered Entity, or | | |
| | (b) Immediately terminate the Agreement and disc Set to the Data Set Recipient and to report the pro Health and Human Services. | | |
| | | | |
| SIGN | ATURES: | | |
| Data S | Set Recipient: | D | Pate: |
| Covere | ed Entity Representative: | D | Pate: |
| DMH : | Privacy Officer: | D | Pate: |